59

(2)

No. 06-1262

FILED
JUN 15 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

KEITH BAKER, Individually, and
IAN BAKER, Individually and as Independent Executor of the Estate of Jean Baker, Deceased,
Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., and ST. JUDE MEDICAL, INC.,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Texas, First District, Houston

---

BRIEF IN OPPOSITION

JAMES C. MARTIN *
STEVEN M. KOHN
LISA M. BAIRD
REED SMITH LLP
355 South Grand Avenue, Suite 2900
Los Angeles, CA 90071-1514
(213) 457-8000

* Counsel of Record

Counsel for Respondents

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether, consistent with *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), the Texas court of appeals correctly held that 21 U.S.C. § 360k(a) preempts petitioners' state law damages claims involving St. Jude Medical, Inc.'s Class III medical device?

CORPORATE DISCLOSURE STATEMENT

Respondent St. Jude Medical, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns ten percent or more of this respondent's stock.

Respondent St. Jude Medical, S.C., Inc. is a wholly owned subsidiary of St. Jude Medical, Inc. No other publicly held company owns ten percent or more of this respondent's stock.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
CORPORATE DISCLOSURE STATEMENT	ii
TABLE OF AUTHORITIES	v
STATEMENT OF THE CASE	3
The Regulatory Bases For Federal Preemption As Applied To Class III Medical Devices	3
REASONS FOR DENYING THE PETITION	11
A. The Petition Incorrectly Represents The Record Regarding The Status Of FDA Approval For The Medical Device In Question	11
B. There Is No Split Of Authority Regarding Preemption Involving Medical Devices That Allegedly Lost FDA Approval After Implantation	12
CONCLUSION	15
APPENDIX A—April 29, 2002 Order Sustaining Objections to Summary Judgment Evidence, *Estate of Jean Baker, Deceased*, In the Probate Court Number One (1) of Harris County, Texas, Case No. 312543-402	1a
APPENDIX B—April 29, 2002 Order, *Estate of Jean Baker, Deceased*, In the Probate Court Number One (1) of Harris County, Texas, Case No. 312543-402	3a
APPENDIX C—June 30, 2005 Opinion, Court of Appeals of Texas, Houston (1st Dist.), *In re Heart Valve Litigation*, 2005 WL 1541059 (Tex.App.-Hous. (1 Dist.))	9a

TABLE OF CONTENTS—Continued

Page

APPENDIX D—February 8, 2006 Notice of Order on Motion, *Ian Baker, et al. v. St. Jude Medical, S.C., Inc., et al.*, Court of Appeals for the First District of Texas at Houston, Case No. 01-02-00802-CV 25a

APPENDIX E—May 2007 Brief for the United States as Amicus Curiae, *Charles R. Riegel, et al. v. Medtronic, Inc.*, U.S. Supreme Court, Case No. 06-179 ..... 27a

TABLE OF AUTHORITIES

CASES Page

Bates v. Dow AgroSciences LLC, 544 U.S. 431 (2005) 14, 15
Brooks v. Howmedica, Inc., 535 U.S. 1056 (2002). 2
Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001) 13, 14
Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) 5
Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005) 13, 14
Fry v. Allergan Med. Optics, 695 A.2d 511 (R.I. 1997) 13, 14
Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999) 13, 14
Green v. Dolsky, 685 A.2d 110 (Pa. 1996) 13, 14
Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004) 13, 14
In re Heart Valve Litigation, 2005 WL 1541059 (Tex. App. June 30, 2005) 9, 10
In re St. Jude Medical, Inc., Silzone Heart Valves Prods. Liab. Lit., 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (MDL No. 01-1396) 13
Kemp v. Medtronic, Inc., 534 U.S. 818 (2001) 3
Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) 5, 13, 14
Knisley v. Medtronic, Inc., 126 S. Ct. 420 (2005). 2
Martin v. Medtronic, Inc., 534 U.S. 1078 (2002).. 2
Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001) 13, 14
McMullen v. Medtronic, Inc., 126 S. Ct. 1464 (2006) 2
McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005) 13, 14
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) 1

TABLE OF AUTHORITIES—Continued

Page

Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997) 5, 13, 14
Papike v. Tambrands Inc., 107 F.3d 737 (9th Cir. 1997) 14
Riegel v. Medtronic Corp., 451 F.3d 104 (2d Cir. 2006) 13
Worthy v. Collagen Corp., 524 U.S. 954 (1998) ... 3
Worthy v. Collagen Corp., 967 S.W.2d 360 (Tex. 1998) ..... *passim*

STATUTES, RULES, AND REGULATIONS

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* 3

Medical Device Amendments (MDA),
21 U.S.C. §§ 360c *et seq.* 3
21 U.S.C. § 360c(a)(1)(C) 4
21 U.S.C. § 360e 4
21 U.S.C. § 360k(a) 1, 4

21 C.F.R. § 814.20(b) 4
21 C.F.R. § 814.39 ..... 4, 5
21 C.F.R. § 814.46 ..... 2, 8, 10, 11

Tex. Bus. & Commerce Code §§ 17.01 *et seq.* .. 9
S. Ct. Rule 10 ..... 12, 13
S. Ct. Rule 14.4 ..... 2, 12

MISCELLANEOUS

Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 11437205 (3d Cir. May 14, 2007) (No. 02-4597) 14, 15

TABLE OF AUTHORITIES—Continued

	Page
Brief for the United States as Amicus Curiae, *Riegel v. Medtronic, Inc.*, No. 06-179 (S. Ct. May 2007)	3, 11
H.R. Rep. No. 94-853 (1976)	3

IN THE

Supreme Court of the United States

No. 06-1262

KEITH BAKER, Individually, and
IAN BAKER, Individually and as Independent Executor of the Estate of Jean Baker, Deceased,
Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., and ST. JUDE MEDICAL, INC.,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Texas, First District, Houston

BRIEF FOR THE RESPONDENTS IN OPPOSITION

Petitioners contend this case presents a good vehicle for the Court to clarify *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and address two questions: whether, under 21 U.S.C. § 360k(a), FDA premarket approval (PMA) of a Class III medical device preempts conflicting state law claims arising from the device's design, manufacture, and labeling, and whether preemption still holds if that approval is subsequently "lost."

But the reasons for denying certiorari in this case are significant. The primary question presented in the petition is whether medical devices that have lost their FDA approval give rise to preemption. Yet that issue depends on an

assertion—that FDA approval was lost—lacking any support in the record. Throughout this case, petitioners have argued that statements in two documents (the "Dee letter" and the "Fitzgerald memo") conclusively establish that the FDA withdrew approval for the medical device in question. But the Texas probate court excluded those statements, and the Texas court of appeals did not disturb that ruling. Opp'n App. 1a-2a, 8a; Pet. App. 1a, 5a-6a & n.4, 11a n.5 (*Baker v. St. Jude Medical S.C., Inc.*, 178 S.W.3d 127, 132 & n.4, 134 n.5 (Tex. App. 2005)). Instead, as the court of appeals expressly recognized, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted." Pet. App. 6a. This discrete and correct evidentiary ruling does not warrant this Court's review, and petitioners' failure to inform this Court of it alone is sufficient reason to deny the petition under Rule 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition.").

Moreover, petitioners' assertions of a "conflict" in the relevant preemption authority do not withstand analysis either. In Texas state courts there is no such split. The controlling preemption analysis, set forth in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), was followed by the courts below. More broadly, the overwhelming majority of federal and state cases follow *Worthy*'s analysis. Accordingly, this Court previously has declined to review cases applying preemption principles to Class III medical devices,[1] and there is no reason, as the

---

[1] *See, e.g., McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002);

Solicitor General recently has noted, to depart from that position now. *See* Opp'n App. 34a-35a (Brief for the United States as Amicus Curiae at 2-3, *Riegel v. Medtronic, Inc.*, No. 06-179 (S. Ct. May 2007)).

In sum, the petition presents a unique fact-bound issue that is, in essence, nothing more than a dispute with the probate court's correct evidentiary ruling. Even if one gets beyond the discrete nature of the dispute, the controlling preemption principles are well settled, and there is no material conflict in the law. The asserted bases for this Court's review are not present and the petition should be denied.

STATEMENT OF THE CASE

The Regulatory Bases For Federal Preemption As Applied To Class III Medical Devices

This case involves a question of federal preemption as applied to a Class III medical device. These devices are the most highly regulated and invoke express preemption principles by virtue of the controlling federal regulatory scheme.

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, which vastly expanded the authority of the FDA to regulate medical devices. At the same time it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That

---

Kemp v. Medtronic, Inc., 534 U.S. 818 (2001); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998).

general prohibition, which also safeguards the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable ... to the device" under federal law. 21 U.S.C. § 360k(a).

To obtain premarket approval, manufacturers must provide the FDA with research results and other data supporting the intended use of the device, a sample of the device, and other information, including the proposed device composition and proposed product labeling. Clerk's Record (CR) 3055-56; *see also* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 814.20(b)). Among other information, a PMA application must include:

- all known reports pertaining to the device's safety and efficacy, § 360e(c)(1)(A);
- a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device, § 360e(c)(1)(B);
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device, § 360e(c)(1)(C);
- samples of the device when practical, § 360e(c)(1)(E); and
- specimens of the labeling proposed to be used for the device, § 360e(c)(1)(F).

CR 3055-56.

Device innovations also receive this same scrutiny. Thus, if a PMA medical device is subsequently modified, the manufacturer must seek approval for the modification through the "PMA supplement" process. CR 3056; *see also* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. All the procedures and actions applicable to a PMA application apply to a PMA

supplement. CR 2791-92 (citing *Worthy*, 967 S.W.2d at 364-65 (describing the PMA supplement process) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (same)). In a PMA supplement, the manufacturer must provide the same information required by a PMA application to support approval of the proposed modifications. CR 3056-57; *see also* 21 C.F.R. § 814.39(c).

PMA and PMA supplement submissions are voluminous, and the FDA's experts evaluate them fully. On average, the FDA spends 1200 hours reviewing a PMA. CR 3056; *see generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344-45 (2001) (describing the PMA process); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (same). When the medical device at issue is a heart valve, the FDA employs a staff of experts in that specific area, and uses standards contained in an FDA document entitled "Replacement Heart Valve Guidance" (Guidance Document).[2] CR 3059.

The medical device at issue in this case was reviewed through these processes. In December 1982, following two years of regulatory review, the FDA approved St. Jude Medical's initial PMA application for a mechanical heart valve, called the "Bi-Leaflet Center Opening Pyrolytic Carbon Cardiac Valve." CR 3161-62. In the years following approval, St. Jude Medical provided the FDA with a tremendous amount of additional data regarding the safety and efficacy of the valves, in a series of PMA supplements. *Id.*

---

[2] The Guidance Document sets forth the type of testing that must be conducted, and the test data that must be submitted, to adequately demonstrate heart valve safety and efficacy in any PMA or PMA supplement application for that type of device. *See* CR 3059. If the manufacturer deviates from the recommended tests and other recommendations, it must demonstrate the equivalency or superiority of its choice of alternative to the satisfaction of the FDA or the FDA will refuse approval. *Id.*

This standard mechanical heart valve achieved wide acceptance. As medical research continued to evolve, however, St. Jude Medical developed innovative new technologies for physicians and their patients, including modifying its heart valve to incorporate a rotating sewing cuff that eliminated the need for surgeons to position the valve prior to suturing. CR 3162. The PMA supplement for this modification, known as the Masters Series valve, was supported by extensive documentation, including proposed labels, design specifications, and manufacturing standards, and the FDA approved it. CR 3162-63.

Over time, it became clear that an additional new technology was needed to address a well-known risk associated with artificial heart valves: endocarditis. CR 3156. Even with aggressive treatment, endocarditis can be life-threatening, causing death in 25% to 60% of cases. *Id.*

Silver, in various forms, has been used as an antimicrobial agent for many years, including as an infection-resistant coating for other medical devices. CR 3157, 3222, 3237. Spire Corporation had developed a patented technology to coat biomaterials with a silver coating several microns thick, subjected the coating to numerous safety and efficacy in vitro (laboratory) and in vivo (patient or animal) tests, and successfully used it on several medical devices. CR 3285-86. Thus, in December 1995, St. Jude Medical preliminarily notified the FDA of its plan to modify its Masters Series valve to incorporate Spire's infection-resistant, sterile silver coating on the sewing cuff. CR 3148, 3163-64, 3285.

The FDA advised St. Jude Medical that its proposed plan required numerous modifications—based in part on the heart valve Guidance Document—including performance of specific tests and submission of additional data and information. CR 3164-65. Almost a year and a half later, in May 1997, after it had compiled the data the FDA specified, St. Jude Medical formally submitted its PMA supplement to add the

silver coating (under the name Silzone®) to the sewing cuff on its Masters Series mechanical heart valve. CR 3165-67.[3]

The FDA's review of the formal PMA supplement took more than 10 months to complete, in addition to the many months the FDA already had spent reviewing St. Jude Medical's preliminary proposal. CR 3167. During this review process, the FDA demanded further testing and data, label changes, and manufacturing changes. CR 3167-70.

In March 1998, the FDA finally approved the PMA supplement, concluding there was sufficient evidence that the Masters Series heart valve with a Silzone®-coated sewing ring was reasonably safe and effective for its intended use. CR 3170-72. Through its approval, the FDA required St. Jude Medical to use the exact design, labeling, and manufacturing process it had approved. *Id.* The FDA also prohibited St. Jude Medical from making claims regarding efficacy of the Silzone® coating in preventing endocarditis pending the completion of further testing. *Id.*

St. Jude Medical thereafter manufactured and marketed the Silzone® valve in conformity with the established requirements. CR 3152, 3173. Petitioners have never adduced any evidence that the specific valve at issue in this case deviated from the FDA-required design, label, or manufacturing process.

---

[3] This application provided important safety and efficacy data regarding the proposed silver coating material, design specifications, a sample package label for the new valve, and details regarding the manufacturing process that would be employed. *See* CR 3165-67. It also included a peer-reviewed report on a human clinical trial of the Silzone® valve. CR 3173-74, 3236. In addition, Spire had submitted to the FDA its own Master File in support of its patented silver coating with additional information on the coating process, quality control procedures, and the results of its own tests, and St. Jude Medical's PMA supplement relied on these materials as well. CR 3166, 3286.

Concomitantly with the marketing of the valve, St. Jude Medical continued to study its efficacy. The largest and most comprehensive of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). CR 3176. An independent data safety and monitoring board (DSMB) periodically reviewed data generated by the AVERT. CR 3176. On January 21, 2000, the DSMB concluded the preliminary data from AVERT indicated that a very small percentage of the patients with the Silzone® valve had an equally small, but statistically significant, increased incidence of explant due to paravalvular leak. CR 3177-78. That same day, St. Jude Medical began a voluntary world-wide recall of all unimplanted Silzone® products.[4] *Id.*

Following St. Jude Medical's voluntary recall, the FDA audited the company but never recommended any change to the company's voluntary recall plan or took formal regulatory action. CR 535-40 ("Current inspection was prompted by a voluntary recall of all unimplanted heart valves with silver ion (silzone) impregnated sewing cuffs . . . . No FDA 483 was issued to this firm. It appears that St. Jude responded quickly to the outcomes of the [redacted] study"); CR 3178. The FDA also never took any of the steps needed to formally revoke approval for the Silzone® valve described in 21 C.F.R. § 814.46. Two FDA officials wrote statements, referred to in this case as the "Dee letter" and "Fitzgerald memo," indicating the company's action met "the formal definition of a 'Recall'" and was in lieu of FDA "legal action to remove the defective products from the market." Pet. App. 38a; *see also* Pet. App. 5a-6a. At the same time, the FDA's position on

---

[4] In connection with this voluntary recall effort, St. Jude Medical alerted the FDA and also sent overnight alert letters to those cardiac surgeons and other physicians known to use its products. CR 3177-78; *see also* CR 1334-43. Those letters asked the recipients to stop using the Silzone® valve and to return any unimplanted Silzone® products. CR 3177-78; *see also* CR 1334-43.

already-implanted valves was that normal monitoring was sufficient to detect the relatively low-risk occurrence reported in the AVERT study. CR 604, 619-23.

Petitioners Keith Baker and Ian Baker filed a lawsuit in Probate Court Number One of Harris County, Texas claiming that their mother's death resulted from negligent care provided by her physicians. CR 925. They also alleged several common law product liability theories and a statutory deceptive trade practices claim (Tex. Bus. & Com. Code Ann. § 17.01 *et seq.* (Vernon 2002 & Supp. 2006)) against St. Jude Medical. CR 946-48. Each of petitioners' claims alleged the heart valve is "an unreasonably dangerous and defective" medical device that should have been manufactured and marketed with a design and label different from the one the FDA approved and required St. Jude Medical to use. *See* CR 947.

St. Jude Medical moved for summary judgment arguing that both express and implied preemption barred the common law and statutory claims. CR 2788-2812. Because the record established the requisite PMA and PMA supplement approval of the Silzone®-coated sewing cuff (CR 1019-1048), the probate court granted summary judgment (Pet. App. 21a). It also upheld several of St. Jude Medical's evidentiary objections and excluded the salient portions of the Dee letter (Pet. App. 37a-41a), and the Fitzgerald memo (Pet. App. 33a-36a). Opp'n App. 1a-2a, 8a. The probate court later denied petitioners' new trial motion and renewed evidentiary arguments. CR 4362.

Afterward, St. Jude Medical also successfully moved for summary judgment on the claims of an additional 69 plaintiffs in a coordinated state court proceeding in Harris County, Texas involving the same Silzone® heart valve. *See* Opp'n App. 9a, 21a-24a (*In re Heart Valve Litigation*, 2005 WL 1541059 (Tex. App. June 30, 2005)).

Petitioners in this case then appealed (CR 4363), and the 69 plaintiffs in the coordinated Texas proceeding filed a companion appeal. The court of appeals affirmed summary judgment both in this case and in the companion appeal, and published its decision in this case. Pet. App. 1a-20a; Opp'n App. 9a-24a. It did not disturb the probate court's exclusion of the Dee letter (Pet. App. 37a-41a), or the Fitzgerald memo (Pet. App. 33a-36a) excerpts. *See* Pet. App. 5a-6a & n.4. It also affirmed on both express and implied preemption grounds. *See id.* at 16a-17a (affirming judgment for St. Jude Medical on negligence, product liability and Texas Deceptive Trade Practices Act claims on express preemption grounds); *id.* at 17a-20a (affirming judgment for St. Jude Medical on fraud claim on implied preemption grounds).

In affirming, the court of appeals expressly recognized that, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and that it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. at 6a.

The court of appeals denied petitioners' motion for rehearing on February 8, 2006. Opp'n App. 25a-26a. Petitioners here then sought discretionary review by the Texas Supreme Court, although the 69 plaintiffs in *In re Heart Valve Litigation* did not. After the parties filed merits briefs, the Texas Supreme Court denied review in this case on December 15, 2006. Pet. App. 22a.[5]

---

[5] In one place, the petition states that "[t]hese issues were appealed directly by the petitioners to the Texas Supreme Court." Pet. 5. But in fact the Texas Supreme Court denied petitioners' discretionary petition for review after full merits briefing on issues such as whether the court of appeals' opinion in this case was a faithful application of the Texas Supreme Court's precedent, *Worthy*, 967 S.W.2d 360. *See* Pet. App. 22a, 110a-112a.

REASONS FOR DENYING THE PETITION

A. The Petition Incorrectly Represents The Record Regarding The Status Of FDA Approval For The Medical Device In Question

The federal regulations provide one avenue by which the FDA may withdraw premarket approval: it must issue formal notice to the medical device manufacturer, hold a hearing, and offer an appeal process. *See* 21 C.F.R. § 814.46. The Texas court of appeals recognized no such steps were taken for the Silzone® device, and thus it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. 6a; *cf.* Opp'n App. 44a (Solicitor General's amicus brief in *Riegel*, describing statutory requirements for FDA to withdraw premarket approval and stating "[w]here the FDA has not taken such action, its approval of the PMA – and the 'requirements' that result from that approval – remain in effect.").

At best, the petition mischaracterizes the appellate court's statement that it was undisputed the FDA never formally withdrew approval. It represents in one place that the Texas court of appeals merely "implied that the Silzone-coated valves must still be FDA-approved" and suggests it was "clearly . . . incorrect" in reaching that conclusion. Pet. 10.

More often, however, the petition represents this case as unequivocally involving the opposite circumstance – that the Silzone® valve undisputedly lost approval – without any acknowledgement of the probate court's contrary evidentiary finding. *See* Pet. 1 ("suppose a particular device is no longer FDA-approved?"); 12 ("Preemption When the Product is No Longer FDA-Approved" and "this product is no longer approved by the FDA"); 13 ("the product no longer has FDA approval").

To make these assertions, petitioners construct an argument based upon the Dee letter and Fitzgerald memo (Pet. 9-11), yet never once acknowledge that those documents were excluded by the probate court, or that their exclusion was left undisturbed by the Texas court of appeals (Pet. App. 5a-6a & n.4, 11a n.5). This omission is not a minor one, given that half the petition is premised on the Dee letter and Fitzgerald memo and results in petitioners' argument that certiorari is warranted because the lower courts upheld preemption for a device that was not FDA-approved.

There is no reason for this Court to grant certiorari to address a putative legal issue not supported by the record in this case. *See* S. Ct. R. 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition."). There also is no reason for this Court to grant certiorari to address the propriety of the probate court's evidentiary ruling. *See* S. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings.").

B. There Is No Split Of Authority Regarding Preemption Involving Medical Devices That Allegedly Lost FDA Approval After Implantation

Even without petitioners' fundamental record problem, the grounds for denying certiorari are ample. According to petitioners, the "opinion of the Texas Court of Appeals is the only published appellate opinion in this country in which a court has directly addressed" the issue of whether preemption applies when a "product is no longer approved by the FDA." Pet. 12. On its face, this question presents no split in authority that can traditionally provide a "compelling reason" under Rule 10 for review.

The vast majority of courts—and *all* recent appellate decisions—have found that premarket approval and the resultant bar on changes to an FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. *See, e.g.*, Pet. App. 11a-16a; *Riegel v. Medtronic Corp.*, 451 F.3d 104 (2d Cir. 2006); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487–88 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163, 171–73 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226–27 (6th Cir.); *Mitchell*, 126 F.3d at 911 (7th Cir.); *Worthy*, 967 S.W.2d at 376 (Tex.); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to these decisions, petitioners identify (at Pet. 1) – but never discuss – an outdated federal court of appeals decision that did not find premarket approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). The decision in *Goodlin*, which arises on facts different from those presented here, is not reflective of the current state of law and is no threat to the stability of the prevailing authority in the Texas state courts or elsewhere.[6]

---

[6] Petitioners also identify one unpublished interlocutory district court order that involved the same medical device as this case and did not find the PMA and PMA supplement process preemptive, *In re St. Jude Medical, Inc., Silzone Heart Valves Prods. Liab. Lit.*, 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (MDL No. 01-1396). (Pet. App. 42a, 77a). But they do not contend that this order is of any significance in terms of a split of authority (Pet. 7-10), nor could they given the order's interlocutory nature and the fact it is only a trial court order that has not yet received appellate review. *See* S. Ct. R. 10 (identifying other compelling circumstances where review is warranted).

In the eight years since *Goodlin* was decided, no other court of appeals and no other state supreme court has joined the Eleventh Circuit. Given the legal and administrative developments in the meantime, there is reason to believe that the Eleventh Circuit will correct itself. *See* Opp'n App. 51a-52a.

The appellate court's decision in this case also does not conflict with this Court's precedent *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). Petitioners argue that "it is not entirely clear" after *Bates* "when requirements might be deemed imposed by state court suits so as to run afoul of preemption provisions." Pet. 25. But once again, the vast majority of lower courts, and *all* courts to have considered the issue recently, have held that, under the MDA, state tort claims can be preempted. *See, e.g.*, Pet. App. 7a-11a; *McMullen*, 421 F.3d at 487; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–77; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–14; *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–18.

Similarly, petitioners contend that "*Bates* made one point abundantly clear: even if a jury verdict in a damages claim were to be based on a finding that would conflict with an agency finding, the verdict would never support application of the preemption doctrine." Pet. 25. But in *Bates*, this Court held that the term "requirements" in the identically-worded Federal Insecticide, Fungicide, and Rodenticide Act includes common law claims. *Bates*, 544 U.S. at 443. This issue thus is also well settled.[7] *See* Opp'n App. 44a-45a (Solicitor

[7] As the FDA explained through the Solicitor General, during the PMA process it conducts "a thorough review of a substantial scientific record" (Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *16 (3d Cir. May 14, 2007) (No. 02-4597)) and performs a "careful balancing" of the benefits and risks associated with a particular

General acknowledging that this Court has consistently held state common law actions can create state "requirements").

Whatever petitioners' confusion about the state requirement side of the preemption analysis, it is not reflected in any recent circuit or state high court decision. There also is no conflict between the appellate court's position and this Court's *Bates* decision. The result reached below likewise comports with the prevailing administrative construction of the pertinent regulatory scheme. Finally, as the FDA has emphasized, "very strong public policy considerations" support application of preemption principles to state common law claims involving Class III medical devices. Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *25 (3d Cir. May 14, 2007) (No. 02-4597). According to the FDA—the agency charged with implementing the MDA—"the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application." Opp'n App. 45a.

CONCLUSION

The petition at bottom asks this Court to revive and resolve a state law evidentiary dispute that does not present a reason to grant certiorari and was not preserved for appeal. Beyond that, it asks this Court to set a Texas court on its proper course without any showing that the preemption principles applied are in need of correction. Even as to the result reached, an examination of the recent and controlling case

---

device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.

law reveals no material conflict in the application of established preemption principles to this unique set of facts. For each of these reasons, the petition should be denied.

Respectfully submitted,

JAMES C. MARTIN *
STEVEN M. KOHN
LISA M. BAIRD
REED SMITH LLP
355 South Grand Avenue, Suite 2900
Los Angeles, CA 90071-1514
(213) 457-8000

* Counsel of Record

Counsel for Respondents

Dated: June 15, 2007

APPENDIX

APPENDIX A

ESTATE OF JEAN BAKER DECEASED

312543-402

IN THE PROBATE COURT NUMBER ONE (1) OF
HARRIS COUNTY, TEXAS

ORDER SUSTAINING OBJECTIONS TO
SUMMARY JUDGMENT EVIDENCE

On this day came on for consideration St. Jude Medical's Objections to and Motion to Strike Plaintiffs' Summary Judgment Evidence, and the Court having reviewed the plaintiffs' Motion for Partial Summary Judgment, St. Jude Medical's objections, and the plaintiffs' response thereto, decided to grant the motion. It is therefore ORDERED that St. Jude Medical's objections to the following summary judgment evidence submitted by plaintiffs in support of their motion for partial summary judgment are hereby sustained, and the following summary judgment evidence is stricken from the record:

~~1. The recall letters sent by St. Jude Medical to its customers (Exhibit B to Plaintiffs' Motion at pages 001374-001380~~; RA

2. The following statements contained in the letter written on March 22, 2000 by Edwin S. Dee to Terry Shepherd, which is part of Exhibit B to plaintiffs' motion at pages 001367-001369:

> "The use of the mechanical heart valves having cuffs with Silzone® Coating has been associated with a statically-higher rate of paravalvular leaks, and with a significantly higher rate of explant due to the endorcarditis.

> We have reviewed your action and conclude that it meets the formal definition of a "Recall". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market."

3. The following statements contained in an FDA internal memorandum dated March 20, 2000 from Mary Ann Fitzgerald to Derk J. Mauw, which is a part of Exhibit C to plaintiffs' motion at pages 300219-300221:

> "We consider the devices to be adulterated and misbranded because there is a statically significantly higher rate of paravalvular leaks with the silver ion (Silzone®) coated sewing cuffs leading to valve explants. The device defects presents a moderate risk of adverse health consequences."

Signed this 29th day of April, 2002.

/s/ Russell P. Austin
HON. RUSSELL P. AUSTIN

APPENDIX B

ESTATE OF JEAN BAKER DECEASED

312543-402

IN THE PROBATE COURT NUMBER ONE (1)
OF HARRIS COUNTY, TEXAS

ORDER

Came on for consideration on this date, St. Jude Medical's objections to the controverting evidence offered by plaintiffs in support of their Response to St. Jude Medical's Motion for Summary Judgment. The Court, after consideration of the objections, hereby ORDERS that the objections are granted or denied as reflected below:

APPENDIX "A"

Granted ✓ Denied _

APPENDIX "B"

Granted ✓ Denied _

AFFIDAVIT OF NEIL VAN HOOYDONK

Page 3, Paragraph 1

The affiant states: "In November 1999, the product was subject to a recall in the United Kingdom for an unexpected incidence of thrombi associated with the use of the product."

Granted _ Denied ✓

Page 3, Paragraph 1

The affiant states: "In addition, an unexpected incidence of paravalvular leaks associated with the product were reported by November 1999 through early Jan 2000."

Granted _ Denied ✓

Page 3, Paragraph 2

The affiant states: "St. Jude was required, as a condition of the PMA Supplement approval, to report these events to the FDA within 5 or 10 days of 'becoming aware' of same. The FDA file does not reflect such notification was timely provided, thus effectuating the automatic invalidation of the PMA Supplement approval pursuant to its express terms."

Granted ✓ Denied _

Page 3, Paragraph 3

The affiant states: "On March 20, 2000, the FDA made a determination that the Silzone® coated St. Jude values as "adulterated" and "misbranded." [site]

Granted ✓ Denied _

Page 3, Paragraph 3

The affiant states: "Two days later, on March 22, 2000, the FDA sent St. Jude a letter advising that the FDA agreed with the voluntary recall, and that it was considered to be in lieu of an FDA action to mandate the immediate withdrawal of the products, which the FDA now considered 'defective,' from the market"

Granted ✓ Denied _

Page 3, Paragraph 4

The affiant states: "Thus, once the FDA made a determination that the product as 'adulterated,' 'misbranded,' and 'defective,' [sic] St. Jude no longer had authorization under any PMA Supplement approval to manufacture, sell, market, or distribute the product with Silzone® coating."

Granted ✓ Denied _

Page 3, Paragraph 5

The affiant states: "The PMA Supplement approval is closer in many aspects some ways to the 510(k) process than the full PMA process. [sic] In this case, the PMA Supplement approval for the subject valve with Silzone coating is more similar to the least stringent approval process, the 510k [sic] process, than the full PMA process."

Granted _ Denied ✓

Page 5, Paragraph 1

The affiant states: "Not absolutely required since 1997, the FDA nonetheless invariably does require, with a full PMA application, that the product be submitted for consideration to an independently appointed Review Committee. . . . This is a very important part of insuring the safety of the device in the FDA approval process."

Granted _ Denied ✓

Pages 6-7, Paragraphs 1 and 3

The affiant states: "Prior to submission of a PMA application to the agency and the Review Committee (where applicable), human clinical studies must be performed

under an approved Investigational Device Exemption (IDE) and the supervision of an Investigational Review Board . . . . The results of the human clinical trials are then submitted and carefully reviewed by both the FDA, and where applicable, the Review Committee. If, after all this study and observation of the product, the FDA determines that the product is both safe and effective, it is approved for marketing under the conditions set by the FDA."

Granted _ Denied ✓

Page 7, Paragraphs 2-6

The affiant gives a lengthy explanation of the 510(k) process.

Granted _ Denied ✓

Page 8, Paragraph 1

The affiant states: "In many respects, the typical PMA Supplement process is much more similar to the 510(k) process than the full PMA process. For example, a PMA Supplement application is often a very abbreviated package, nowhere near the volume of a full PMA application. In addition, rarely is an Independent Review Committee appointed to review a PMA Supplement application. Finally, rarely is the manufacturer required to subject a product to human clinical trials in a PMA Supplement application."

Granted _ Denied ✓

Page 8, Paragraph 2

The affiant states: "The PMA Supplement Application for the subject valves reflects nowhere near the rigorous process that would be required for the full PMA ap-

proval. This is evidenced by the fact that the original PMA application consists of three file boxes of documentation and the supplement is about two inches thick. A full PMA application would certainly be larger than what was submitted in this case for the subject "valves."

Granted ✓ Denied _

Page 8, Paragraph 3

The affiant states: "If the agency had elected to submit this supplement to a review committee, it is my opinion that the review committee would have recommended disapproval of the application until such time that clinical trials had been performed establishing reasonable assurance of safety and effectiveness."

Granted _ Denied ✓

Page 9, Paragraph 2

The affiant states: "If SJM had followed the FDA guidelines there is a reasonable probability that evidence of bio-incompatibility would have been identified."

Granted ✓ Denied _

Page 9, Paragraph 3

The affiant states: "In my expert opinion, a PMA Supplement application for a design change is not as rigorous in as a full PMA application." [sic]

Granted _ Denied ✓

Page 9, Paragraph 4

The affiant states: "In this case for the subject valves, for the reasons as set out above, the PMA Supplement

application was not as rigorous as it would have been had the modified product gone through the full PMA process. Moreover, the review of the safety and efficacy of the proposed change by the FDA was not nearly as thorough and rigorous as it would have been had the product been submitted to a full PMA approval. Due to the: (a) short application; (b) complete absence of clinical human studies; (c) complete absence of Advisory Committee review and oversights; and (d) shortcut animal studies; it is my expert opinion that the PMA Supplement process in this case was neither rigorous nor thorough, and that it was much closer to a 510(k) approval than a full PMA approval."

Granted _ Denied ✓

FDA DOCUMENTS

a. March 20, 2000. Letter from Edwin S. Dee (the "Dee letter")

Granted ✓ to the extent of Order Sustaining Objection to S/J Evidence Denied _

b. March 22, 2000. Memorandum from Mary Ann Fitzgerald (the "Fitzgerald memo")

Granted ✓ to the extent of Order Sustaining Objection to S/J Evidence Denied _

Signed this 29th day of April, 2002.

/s/ Russell P. Austin
HON. RUSSELL P. AUSTIN

APPENDIX C

COURT OF APPEALS OF TEXAS,
HOUSTON (1ST DIST.)

(Cite as: 2005 WL 1541059 (Tex.App.-Hous. (1 Dist.)))

In re HEART VALVE LITIGATION

HOWARD BOYLE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LAVERNE BROWN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SAUNAIE BROWN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JACK CALHOUN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ARTURO CARDENAS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

NEIL CHANDLER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RONALD COOPER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DANIEL DIXON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARY JANETTE DOWELL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GLORIA EVERITT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ELIDA FLORES,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT FOLTZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EARL FUTRELLE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

CAROLYN GIBBENS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RICHARD GILBERT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

CLIFFORD HAMILTON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EDGAR HENDERSON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LINWOOD HEBERT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee,

FRANCIS HITESHEW,

Appellant.

v.

ST. JUDE MEDICAL, INC.,

Appellee.

THOMAS HOVANEC,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

STEVEN HUGGHINS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JAMES IVIE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DAMON KOEN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

FRAN LANE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

WILLIAM LEWELLYN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GLADYS LIPSCOMB,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT LOPEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

BEULAH MALINA,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARIO MARTINEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RAMIRO MARTINEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JANIE MCDANIEL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

PHILIP MEUSER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JAVIER MUNOZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

TONY NAVARRO,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

HUMBERTO NUNEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARY ONESTY,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

BELINDA PEREZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

WESLEY PERREN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GERALD PETSCH,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SANDELLA PHILLIPS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOHNNEY POLLAN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

OSCAR RAMIREZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LILLIE REED,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

FRANK RIOS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

PETRA RODRIGUEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

HENRY ROTHSCHILD,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EARL SADLER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DAVID V. SALAS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SYLVIA SANCHEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LEE A. SIAS, VERNELL SIAS, WILLIAM CRON, NORMAN HAUGEN, GLENDA BREWER, JARVIS CHRISTIAN, BILLY BAKER, RONNIE KING, JANET KING, DONALD IRVIN, SANDRA K. SAM, AND KENNETH E. KANTOROWICZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARTIN SOUTHWICK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOHN STARK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROGER STEWART,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT STROBEL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MOLLY TAPIA,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOSE R. VALENTIN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

OLA MAE WILLIAMS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ELIANA ZADIK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

Nos. 01-03-00198-CV, 01-04-00291-CV, 01-04-00292-CV, 01-04-00293-CV, 01-04-00294-CV, 01-04-00295-CV, 01-04-00296-CV, 01-04-00297-CV, 01-04-00298-CV, 01- 04-00299-CV, 01-04-00300-CV, 01-04-00301-CV, 01-04-00302-CV, 01-04-00303-CV, 01-04-00304-CV, 01-04-00305-CV, 01-04-00306-CV, 01-04-00307-CV, 01-04-00308-CV, 01-04-00309-CV, 01-04-00310-CV, 01-04-00311-CV, 01-04-00312-CV, 01-04-00313-CV, 01-04-00314-CV, 01-04-00315-CV, 01-04-00316-CV, 01-04-00317-CV, 01-04-00318-CV, 01-04-00319-CV, 01-04-00320-CV, 01-04-00321-CV, 01-04-00322-CV, 01-04-00323-CV, 01-04-00324-CV, 01-04-00325-CV, 01-04-00326-CV, 01-04-00327-CV, 01-04-00328-CV, 01-04-00329-CV, 01-04-00330-CV, 01-04-00331-CV, 01-04-00332-CV, 01-04-00333-CV, 01-04-00334-CV, 01-04-00335-CV, 01-04-00336-CV, 01-04-00337-CV, 01-04-00338-CV, 01-04-00339-CV, 01-04-00340-CV, 01-04-00341-CV, 01-04-00342-CV, 01-04-00343-CV, 01-04-00344-CV, 01-04-00345-CV, 01-04-00346-CV, 01-04-00347-CV.

June 30, 2005

On Appeal from the 215th District Court, Harris County, Texas, Trial Court Master Cause Nos.2002-27580-A, 2002-02993-A, 2002-02970-A.

On Appeal from the 113th District Court, Harris County, Texas, Trial Court Cause No.2002-26969-A.

On Appeal from the 127th District Court, Harris County, Texas, Trial Court Cause

Nos.2002-02865-A, 2002-02966-A, 2002-02977-A, 2002-02979-A, 2002- 02978-A.

On Appeal from the 125th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02867-A, 2002-02982-A.

On Appeal from the 295th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02981-A, 2002-42469-A, 2002-02994-A, 2002-26965-A.

On Appeal from the 270th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26971-A, 2002-02976-A, 2002-02963-A.

On Appeal from the 269th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26968-A, 2002-02972-A, 2002-02869-A.

On Appeal from the 334th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26961-A, 2002-02961-A.

On Appeal from the 333rd District Court, Harris County, Texas, Trial Court Cause Nos.2002-26962-A, 2002-02992-A, 2002-55917-A.

On Appeal from the 61st District Court, Harris County, Texas, Trial Court Cause Nos.2002-26970-A, 2002-42468-A.

On Appeal from the 152nd District Court, Harris County, Texas, Trial Court Cause Nos.2002-02987-A, 2002-02962-A, 2002-26963-A.

On Appeal from the 133rd District Court, Harris County, Texas, Trial Court Cause Nos.2002-02964-A, 2002-02968-A.

On Appeal from the 55th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26967-A, 2002-02871-A, 2002-42470-A, 2002-02973-A.

On Appeal from the 129th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02975-A, 2002-02872-A, 2002-02960-A.

On Appeal from the 280th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02991-A, 2002-02863-A.

On Appeal from the 281st District Court, Harris County, Texas, Trial Court Cause Nos.2002-02870-A, 2002-02980-A.

On Appeal from the 157th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02866-A, 2002-02652-A.

On Appeal from the 1 1 th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02965-A, 2002-02971-A.

On Appeal from the 80th District Court, Harris County, Texas, Trial Court Cause No.2002-03213-A.

On Appeal from the 151st District Court, Harris County, Texas, Trial Court Cause Nos.2002-02969-A, 2002-026966-A, 2002-02986-A, 2002-02959-A.

On Appeal from the 165th District Court, Harris County, Texas, Trial Court Cause No.2002-02967-A.

On Appeal from the 234th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02985-A, 2002-26959-A.

On Appeal from the 164th District Court, Harris County, Texas, Trial Court Cause No.2002-46754-A.

On Appeal from the 189th District Court, Harris County, Texas, Trial Court Cause No.2002-02990-A.

On Appeal from the 190th District Court, Harris County, Texas, Trial Court Cause No.2002-02868-A.

MEMORANDUM OPINION

SHERRY RADACK, *Chief Justice.*

The plaintiffs in these appeals were implanted with allegedly defective heart valves, which were manufactured by St. Jude Medical, Inc. (St. Jude) and Spire Corporation (Spire). St. Jude and Spire filed motions for summary judgment, in which they contended that plaintiffs' claims were preempted by their compliance with the Food and Drug Adminis-

trations's pre-market approval procedures for certain medical devices. The trial court granted the manufacturers' motions for summary judgment and these appeals followed. We affirm.

Factual Background

In 1982, the FDA approved St. Jude's initial PMA application for a mechanical heart valve. During the following years, St. Jude made several improvements to the valve, which were also approved through a series of PMA supplements. One of these improvements was the incorporation of a rotating sewing cuff, which eliminated the need for surgeons to position the valve before sewing it in place.

In an effort to combat endocarditis, a life-threatening infection of the heart muscle, St. Jude notified the FDA that it planned to develop a mechanical heart valve with an infection-resistant, sterile, silver coating on the sewing cuff. St. Jude contracted with Spire to use Spire's patented ion beam assisted deposition process to apply a thin silver coating to St. Jude's heart valves. In May 1997, after an FDA-required animal test was completed, St. Jude submitted a PMA supplement to add the Silzone[1] coating to its already approved heart valve.

In March 1998, the FDA approved St. Jude's PMA supplement. As a part of its approval, the FDA imposed several post-approval requirements, including how the valve could be marketed. Specifically, the FDA prohibited St. Jude from making any claims about the efficacy of the Silzone coating in preventing endocarditis. St. Jude began marketing the Silzone valve accordingly.

St. Jude, however, continued to participate in studies to determine the efficacy of the Silzone coating in preventing

---

[1] Silzone® is the trademark name for the sterile, silver coating that St. Jude added to the sewing cuff of its heart valve.

endocarditis. One of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). On January 21, 2000, an independent board reviewing the AVERT data concluded that patients with the Silzone valve were more likely to experience a post-operative complication, known as a paravalvular leak. Approximately 2% of the patients with the Silzone valve experienced such leaks, as opposed to .25% of patients with conventional valves.

The same day it became aware of the conclusions of the AVERT monitoring board, St. Jude began a voluntary recall of all non-implanted Silzone valves, and so informed the FDA. In response, the FDA, in a letter from Edwin Dee to St. Jude, stated, "We agree with your firm's decision to recall [the Silzonevalve] . . . We have reviewed your action, and conclude that it meets the formal definition of a 'Recall'". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." It is undisputed, however, that the FDA never formally withdrew its PMA approval of the valve, and that the valve had FDA approval on the date it was implanted in each of the plaintiffs.

Plaintiffs filed these suits against St. Jude based on theories of liability including, but not limited to, negligence, product liability, and breach of warranty. St. Jude filed a motion for summary judgment, contending that the plaintiffs' state-court tort claims were preempted by the FDA's federal regulation over the valves at issue. The trial court agreed and granted St. Jude's motion for summary judgment.

Analysis

In *Baker v. St. Jude Medical, Inc.*, No. 01-02-00802-CV (Tex.App.-Houston [1st Dist.] June 30, 2005, no pet. h.), which we issue concurrently with this opinion, this Court considered the same arguments as those in these appeals. Specifically, the Court addressed the issue of whether the

plaintiffs' claims in that case were preempted by St. Jude's compliance with applicable FDA pre-market approval procedures. On a record that is nearly identical to that before us in these appeals, this Court concluded that the plaintiffs' negligence, products liability, deceptive trade practices, fraud, and malice claims were, in fact, preempted by St. Jude's compliance with the FDA's pre-market approval process for the manufacture and distribution of the heart valve that was implanted in the plaintiff. See Baker, slip op. at 18, 21. Accordingly, we affirmed the summary judgment granted in favor of St. Jude. *Id.* at 21.

This Court's opinion in *Baker v. St. Jude* extensively discusses the Court's reasoning behind its conclusion that the doctrine of preemption applies. Neither the briefing nor the record in these appeals shows a reason to distinguish the present cases from Baker.

Accordingly, for the reasons given in *Baker v. St. Jude*, we overrule plaintiffs' sole issue on appeal. Because we have held that all of plaintiffs' claims against St. Jude are preempted by federal law, we affirm the judgments.

APPENDIX D

[LOGO] COURT OF APPEALS FOR THE
FIRST DISTRICT OF TEXAS AT HOUSTON

NOTICE OF ORDER ON MOTION

Cause number: 01-02-00802-CV

Style: Ian Baker, ind. & Representative of Estate of Jean Baker v St. Jude Medical S.C.; St. Jude Medical, Inc.

Date motion filed: July 15, 2005

Type of motion: Motion for rehearing

Party filing motion: Appellant

Document to be filed: _____

If motion to extend time:

Deadline to file document: _____

Number of previous extensions granted: _____

Length of extension sought: _____

Ordered that motion is:

☐ Granted
If document is to be filed, document due:

☐ The Clerk is instructed to file the document as of the date of this order

☐ Absent extraordinary circumstances, the Court will not grant additional motions to extend time

☑ Denied

☐ Dismissed (e.g., want of jurisdiction, moot)

Judge's signature: /s/ Sherry Radack

☑ Acting individually ☐ Acting for the Court

Panel consists of Chief Justice Radack Justices Jenning and Higley.

Date: February 08, 2006

---

* Absent emergency or a statement that the motion is unopposed, must wait ten days before acting on motion except for motion to extend time to file a brief. *See* TEX. R. APP. P. 10.3(a).

Note: Single justice may grant or deny any request for relief properly sought by motion, except in a civil case a single justice should not: (1) act on a petition for an extraordinary writ or (2) dismiss or otherwise determine an appeal or a motion for rehearing. TEX. R. APP. P. 10.4(a).

APPENDIX E

IN THE SUPREME COURT OF THE UNITED STATES

No. 06-179

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

PAUL D. CLEMENT
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
MALCOLM L. STEWART
Assistant to the Solicitor General
DOUGLAS N. LETTER
SHARON SWINGLE
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

DANIEL MERON
General Counsel

SHELDON T. BRADSHAW
Associate General Counsel
Department of Health and Human Services
Rockville, MD 20857

QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of the device.

TABLE OF CONTENTS

	Page
Statement	1
Discussion	7
A. The decision of the court of appeals is correct	8
B. The decision of the court of appeals does not warrant review	18
Conclusion	20

TABLE OF AUTHORITIES

Cases: Page

Bates v. Dow Agroscis. LLC, 544 U.S. 431 (2005)..... 12, 14, 15, 16, 19
Brooks v. Howmedica, Inc.: 535 U.S. 1056 (2002)..... 20
273 F.3d 785 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002) 18
Collagen Corp. v. Green, 520 U.S. 1212 (1997)... 20
Fry v. Allergan Med. Optics: 522 U.S. 952 (1997)..... 20
695 A.2d 511 (R.I.), *cert. denied*, 522 U.S. 952 (1997)..... 18
Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)..... 18
Green v. Dolsky: 520 U.S. 1168 (1997) 20
685 A.2d 110 (Pa. 1996), *cert. denied*, 520 U.S. 1168, and 520 U.S. 1212 (1997)..... 18
Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004)..... 17, 18
Kemp v. Medtronics, Inc.: 534 U.S. 818 (2001).... 20
231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001) 18
Knisley v. Medtronic, Inc.: 126 S. Ct. 420 (2005)... 20
Martin v. Medtronic, Inc.: 534 U.S. 1078 (2002).. 20
234 F.3d 573), (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002) 18
McMullen v. Medtronic, Inc.: 126 S. Ct. 1464 (2006)..... 20
421 F.3d 482 (7th Cir. 2005), *cert. denied*, 126 S. Ct. 1464 (2006)..... 18
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)..... *passim*
Niehoff v. Surgidev Corp., 950 S.W.2d 816 (Ky. 1997), *cert. denied*, 523 U.S.C. 1005 (1998)..... 19

TABLE OF AUTHORITIES—Continued

	Page
Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997)	19
Smith Indus. Med. Sys., Inc. v. Kernats, 522 U.S. 1044 (1998)	16
State ex rel. Miller v. New Womyn, Inc., 679 N.W.2d 592 (Iowa 2004)	19
Weiland v. Telectronics Pacing Sys., 721 N.E.2d 1149 (Iii. 1999)	18
Worthy v. Collagen Corp.: 524 U.S. 954 (1998)... 967 S.W.2d 360 (Tex.), *cert. denied*, 524 U.S. 954 (1998)	20 18
Statutes and regulations:	
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.	1
21 U.S.C. 331(a)-(c)	14
21 U.S.C. 352(a)	14
21 U.S.C. 352(j)	14
21 U.S.C. 360(k)	2
Medical Device Amendments, 21 U.S.C. 360c *et seq.*	1
21 U.S.C. 360c(a)(1)	2
21 U.S.C. 360c(a)(1)(C)	2
21 U.S.C. 360c(a)(2)	3
21 U.S.C. 360c(a)(2)(B)	11
21 U.S.C. 360c(a)(2)(C)	11
21 U.S.C. 360e(a)(1) (2000 & Supp. IV 2004)	2
21 U.S.C. 360e(b)(1)(A)	2
21 U.S.C. 360e(c)(1)	2
21 U.S.C. 360e(d)(1)(A)	3, 11, 16
21 U.S.C. 360e(d)(1)(B)	3
21 U.S.C. 360e(d)(2)(A)	3
21 U.S.C. 360e(d)(2)(A)-(E)	11

TABLE OF AUTHORITIES—Continued

	Page
21 U.S.C. 360e(d)(2)(B)	3
21 U.S.C. 360e(d)(2)(D)	3
21 U.S.C. 360e(d)(6)	3
21 U.S.C. 360e(e)(1)(A)	12
21 U.S.C. 360e(e)(1)(B)	12
21 U.S.C. 360e(e)(1)(F)	12
21 U.S.C. 360j(e)(1)	3
21 U.S.C. 360k	8, 17, 19
21 U.S.C. 360k(a)	4, 12, 15, 16, 19
21 U.S.C. 360k(a)(1)	5, 11, 13
21 U.S.C. 360k(a)(2)	13
21 U.S.C. 360k(b)	4, 16
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136v(b)	14
21 C.F.R.:	
Section 14.171	2
Section 814.20	2
Section 814.20(b)(13)	2
Section 814.39	3
Section 814.39(d)	3
Section 814.39(d)(1)	3
Section 814.39(d)(2)	3
Section 814.44(d)(1)	3
Section 814.45(c)	2
Section 814.80	3
Section 814.82	3
62 Fed. Reg. (1997):	
p. 65,384	17
p. 65,387	17
63 Fed. Reg. 39,789 (1998)	17
71 Fed. Reg. 3935 (2006)	17

IN THE SUPREME COURT OF THE UNITED STATES

No. 06-179

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE**

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States. In the view of the United States, the decision of the court of appeals is correct and does not warrant review by this Court.

STATEMENT

1. This case presents the question whether premarket approval of a Class III medical device by the Food and Drug Administration (FDA) preempts state-law tort claims premised on allegations that the device in question is unsafe or ineffective. The device at issue in this litigation—the Evergreen Balloon Catheter—is a medical device regulated by the FDA pursuant to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* The FDCA identifies three classes of medical devices, each subject to a

different level of regulation. See 21 U.S.C. 360c(a)(1); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-477 (1996). The Evergreen Balloon Catheter is a Class III device, see 21 U.S.C. 360c(a)(1)(C), and is accordingly subject to the most stringent regulatory controls. With exceptions that are not implicated here, the manufacturer of a Class III device must obtain FDA approval of a premarket approval (PMA) application before marketing the device. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); *Lohr*, 518 U.S. at 477.[1]

In order to obtain premarket approval for a Class III medical device, a manufacturer must submit a PMA application containing full reports of investigations of the device's safety and effectiveness; a statement of the components and principles of operation of the device; a comprehensive description of the methods of manufacture, processing, packing, and installation of the device; and the proposed labeling for the device. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. In determining whether to approve a PMA application, the FDA considers the information submitted by the manufacturer as well as other information known to the agency. See 21 C.F.R. 814.45(c). The FDA may also request additional information from the manufacturer, and it may consult with a scientific advisory committee made up of outside experts. 21 C.F.R.

---

[1] As the Court explained in *Lohr*, see 518 U.S. at 477-478, two categories of Class III devices may be marketed without PMA approval by the FDA. First, devices that were already being marketed for use at the time of the MDA's enactment may continue to be marketed until the FDA issues an applicable regulation requiring submission of a PMA. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); 21 U.S.C. 360e(b)(1)(A); *Lohr*, 518 U.S. at 477-478. Second, a new device that is "substantially equivalent" to a device that is already lawfully on the market may enter the market through FDA clearance of a premarket submission commonly referred to as a "510(k)." See 21 U.S.C. 360(k); *Lohr*, 518 U.S. at 478. Those provisions of the FDCA do not apply in this case, since the Evergreen Balloon Catheter is a post-MDA device for which PMA approval was required.

14.171, 814.20(b)(13). The agency conducts a rigorous review of requests for premarket approval, devoting an average of 1200 hours to each application. See *Lohr*, 518 U.S. at 477.

The FDA grants premarket approval for a Class III device only if, *inter alia*, the agency finds that there is a "reasonable assurance of safety and effectiveness" when the device is used in accordance with the conditions of use included in the proposed labeling, and that the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A); see 21 U.S.C. 360e(d)(2)(A), (B) and (D). In determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B); 21 C.F.R. 814.82, and it may impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1). After a manufacturer has received premarket approval for a Class III medical device, it must submit a supplemental application to the FDA before making any changes to the device that affect the device's safety or effectiveness. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39, 814.80. With narrow exceptions, the manufacturer must receive the FDA's approval before making any such changes.[2]

---

[2] For a narrow class of changes, the manufacturer may submit a "Changes Being Effected" application, setting out in detail the proposed change and the data or information that supports it. See 21 C.F.R. 814.39(d). Unless the FDA rejects the "Changes Being Effected" application within a specified period, the manufacturer may implement the proposed change prior to FDA action on the application, see 21 C.F.R. 814.39(d)(1), although the FDA retains the authority to reject the application and to require the manufacturer to stop distributing the product with the change. Among the types of changes that are eligible for a "Changes Being Effected" application are labeling changes that add or strengthen a warning, as well as changes in quality control or manufacturing process

The FDCA contains an express preemption provision. That provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). The FDA is authorized to exempt from preemption certain State or local requirements for a device. See 21 U.S.C. 360k(b).

2. The Evergreen Balloon Catheter is a Class III medical device manufactured by respondent Medtronic, Inc. Pet. App. 3a. It is used during angioplasties to open patients' clogged arteries. *Ibid.* The device received premarket approval from the FDA in 1994. *Ibid.* In 1995 and 1996, the FDA approved respondent's supplemental applications for revised labeling for the device. *Id.* at 3a-4a.

Petitioner Charles Riegel suffered extensive injuries after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. Pet. App. 4a. He and his wife, petitioner Donna Riegel, brought suit in federal court against respondent. *Ibid.* Petitioners' complaint alleged negligent design, testing, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. *Id.* at 4a-5a. The district court held that all of petitioners' claims

---

that provide additional assurance of purity, identity, strength, or reliability of the device. See 21 C.F.R. 814.39(d)(2).

except those for negligent manufacturing and breach of express warranty were preempted by 21 U.S.C. 360k(a). See Pet. App. 55a-74a. The court subsequently granted respondent's motion for summary judgment on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a.

The court of appeals explained that the premarket approval process for Class III medical devices is "lengthy and rigorous," requiring each manufacturer to provide extensive information establishing the safety and effectiveness of its device. See Pet. App. 8a-9a. The court further observed that "[t]here is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process," *id.* at 8a, and that the FDA is authorized to impose additional requirements as conditions of premarket approval in order to ensure that the device is safe and effective, *id.* at 9a. The court explained as well that, once the FDA approves an application for premarket approval, federal law requires the manufacturer to comply with the specifications set forth in the application and the approval order. See ibid.

In holding that the bulk of petitioners' claims were preempted, the court of appeals construed the term "requirement" in 21 U.S.C. 360k(a)(1) to encompass product specifications set forth in the PMA application that was submitted by respondents and approved by the FDA. See Pet. App. 26a-28a. The court explained that, if the FDA had viewed respondent's proposed product specifications as inadequate to ensure safety and efficacy, the agency could have imposed additional requirements as conditions of premarket approval. *Id.* at 27a-28a. The court recognized that the approved specifications for the Evergreen Balloon Catheter had been fashioned by respondent rather than devised by the FDA, see *id.* at 28a, but it found that fact to be irrelevant to the preemption analysis. The court explained that, "[o]nce the PMA process is complete, all PMA-approved devices are

subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications." *Ibid.*

The court of appeals further held that the imposition of tort liability based on the allegedly defective character of the device would have the practical effect of subjecting the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. The court noted that the claims held to be preempted "do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter." *Id.* at 32a. Rather, the court explained,

> a verdict in [petitioners'] favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

Id. at 33a. The court further noted that its conclusion that such tort claims are preempted is supported by the FDA's position on the preemption question. *Id.* at 37a-38a.

The court of appeals also concluded that the FDA's grant of premarket approval is significantly different, for purposes of preemption analysis, from the substantial-equivalence determination (see note 1, *supra*) that was at issue in *Lohr*. See

Pet. App. 24a-27a. The court noted that premarket approval, unlike a finding of substantial equivalence, reflects the FDA's considered judgment that there is reasonable assurance that the device at issue is safe and effective. See *id.* at 25a. The court further observed that, whereas a substantial-equivalence finding "does not reflect the FDA's determination that the device should 'take any particular form for any particular reason,' the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective." *Id.* at 26a (quoting *Lohr*, 518 U.S. at 493). The court also explained that manufacturers of devices for which a substantial-equivalence finding has been made "have broader latitude to make changes without FDA approval than do manufacturers of PMA [-]approved devices." *Id.* at 26a-27a.[3]

Judge Pooler filed an opinion concurring in part and dissenting in part. Pet. App. 43a-54a. While characterizing the preemption issue presented in this case as a "close question," *id.* at 43a, Judge Pooler would have held that petitioners' claims are not preempted, see *id.* at 50a-53a.

DISCUSSION

The court of appeals correctly held—in accordance with the FDA's interpretation of the FDCA, see Pet. App. 37a-

[3] The court of appeals "agree[d] with the district court's conclusion that [petitioners'] negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. The court explained that "[a] jury verdict in [petitioners'] favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for [respondent's] alleged deviation from those standards." *Id.* at 35a-36a. The court of appeals affirmed the district court's grant of summary judgment to respondent on the merits of the negligent-manufacturing claim, however, see *id.* at 38a-43a, and petitioners do not challenge that ruling in this Court.

38a—that the FDA's premarket approval of a Class III medical device imposes federal "requirements" that preclude the imposition of state-law tort liability based on respondent's alleged failure to satisfy inconsistent or additional state-law requirements. The Second Circuit's decision in this case accords with the large majority of federal and state appellate rulings on the question presented here. Although one federal court of appeals and one state supreme court have held that comparable tort claims were not preempted, those decisions predate most of the other cases addressing the question, and they were issued without the benefit of FDA's current judgment that premarket approval of a Class III device imposes federal "requirements" that should be given preemptive effect. In light of those intervening developments, the courts that have previously rejected preemption defenses in this context may reconsider their position in an appropriate case. This case, moreover, would not be an appropriate vehicle in which to address the preemption of state tort suits concerning Class III devices that have received PMA approval. See pp. 14- 15, *infra*. Review by this Court therefore is not warranted.

A. The Decision Of The Court Of Appeals Is Correct

Petitioners contend (Pet. 19-22) that the court of appeals' ruling in this case is inconsistent with this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Lohr*, however, does not govern this case.

1. In *Lohr*, this Court considered the application of the MDA's express preemption provision, 21 U.S.C. 360k, to a tort suit involving a medical device for which the FDA had made a substantial-equivalence determination. See 518 U.S. at 480-481. In rejecting the manufacturer's claim that the suit was preempted, the Court explained that the process by which substantial-equivalence findings are made "is by no means comparable to the PMA process," involving an average of 20 hours of review time in contrast to the 1200 hours spent on the average PMA review. *Id.* at 478-479. The Court

also noted the FDA's own admonition that its substantial-equivalence determination "should not be construed as an endorsement of the [device]'s safety." *Id.* at 480.

The manufacturer in *Lohr* argued that the FDA's promulgation of general standards for labeling and manufacturing of medical devices "pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." 518 U.S. at 486 (plurality opinion). All Members of this Court agreed that the statute does not impose that blanket prohibition on the imposition of state-law tort liability. See *id.* at 487 (plurality opinion); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The manufacturer also argued, inter alia, that the FDA's clearance of a device based on a substantial-equivalence determination preempted suits alleging that the device was defectively designed. See *id.* at 492 (opinion of the Court). In rejecting that contention, the Court explained that "[t]he company's defense exaggerates the importance of the [substantial-equivalence] process," *ibid.*, and that the device at issue had "never been formally reviewed [by the FDA] under the MDA for safety or efficacy," *id.* at 493. Accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

A four-Justice plurality of the *Lohr* Court predicted that any common-law suits preempted by Section 360k would be "few" and "rare." 518 U.S. at 502. In his concurring opinion, however, Justice Breyer stated that "ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care imposed by a state-law tort action." *Id.* at 504-505. Justice Breyer further stated that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Id.* at 508. The remaining four Justices "conclude[d] that state common-law damages

actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the [FDCA]." *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Those Justices also expressed disagreement with the plurality's forecast that instances of such preemption would be "rare." *Ibid.* Thus, five Members of the Court in *Lohr* agreed that state tort suits are preempted on essentially the same terms as state prescriptive requirements.

The Court in *Lohr* also noted the significant role of the FDA in defining the MDA's preemptive scope. The Court explained:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), and, therefore, whether it should be pre-empted.

518 U.S. at 496 (footnote omitted). The Court concluded that, with respect to the construction of the FDCA's express preemption provision, "[t]he ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a sound basis for giving substantial weight to the agency's view of the statute." *Ibid.* (citation and internal quotation marks omitted).

2. In the instant case, the court of appeals held that the FDA's premarket approval of the Evergreen Balloon Catheter imposed specific federal "requirements" that preempted inconsistent duties sought to be imposed through application of state tort law. See Pet. App. 25a-29a. That holding is correct and is consistent with this Court's decision in *Lohr*.

The FDA's premarket approval for the Evergreen Balloon Catheter was premised on the agency's finding that there was reasonable assurance that the device was safe and effective under the conditions of use prescribed, recommended, or suggested in the labeling of the device and that the labeling was neither false nor misleading. 21 U.S.C. 360c(a)(2)(B), 360e(d)(1)(A) and (2)(A)-(E); see Pet. App. 25a, 27a-28a. Once the device was approved, moreover, respondent could not lawfully implement any changes that would affect the safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior FDA approval). See *id.* at 26a; p. 3 and note 2, *supra*. Because the specifications contained in respondent's application were binding on the manufacturer once the application had been approved, and because the FDA's PMA approval reflected the agency's considered judgment as to the product's safety and efficacy, the court of appeals correctly held that those specifications constitute federal "requirement[s]" within the meaning of Section 360k(a)(1).

Moreover, in determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The court of appeals' ruling thus is fully consistent with *Lohr*, in which the Court distinguished the facts before it from a case, such as this one, "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers." 518 U.S. at 501.

As the court of appeals explained, if the FDA had determined that the device as described in respondent's application was not safe and effective, the agency could have conditioned its grant of premarket approval on respondent's agreement to

undertake specified modifications. Pet. App. 27a-28a. A product specification devised by the FDA and imposed as a condition of authority to market a medical device would constitute a federal "requirement" that would preempt state efforts to impose inconsistent or additional common-law duties. The court of appeals correctly recognized that respondent should not be subject to *greater* potential tort liability simply because the FDA had "deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form" and therefore had declined to impose additional conditions. *Id.* at 28a.

The FDCA also specifically addresses the possibility that new information might come to light that would call into question whether a previously approved device meets the Act's requirements for PMA approval. Once again, however, the FDCA vests responsibility for taking action in the FDA, based on its evaluation of the information and weighing of the relevant considerations. The Act thus authorizes the FDA to withdraw its PMA approval of a device if the agency finds that the device is unsafe or ineffective, or if the agency finds, on the basis of new information evaluated together with information available to it when it approved the application, that the requisite showing of reasonable assurance that the device is safe and effective is lacking, or that the labeling is false or misleading in any particular and was not corrected within a reasonable time after receipt from the FDA of notice of that fact. See 21 U.S.C. 360e(e)(1)(A), (B) and (F). Where the FDA has not taken such action, its approval of the PMA—and the "requirements" that result from that approval—remain in effect.

The court of appeals also correctly held that petitioners' tort suit seeks to impose state "requirement[s]," within the meaning of Section 360k(a), that relate to safety or efficacy and are different from the federal requirements that apply to the Evergreen Balloon Catheter. See Pet. App. 30a-35a. As

the court of appeals recognized, this Court in construing similarly worded federal preemption provisions "has held firm to the view that state 'requirements' can be created by state common law actions." *Id.* at 31a; see, *e.g.*, *Bates v. Dow Agroscis. LLC*, 544 U.S. 431, 443 (2005); see also *Lohr*, 518 U.S. at 503-504 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part). The claims that the court of appeals held to be preempted do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the specifications in the approved PMA application. Rather, they all rest on the allegation that the Evergreen Balloon Catheter, in the form approved by the FDA, "is in some way defective and therefore requires modification." Pet. App. 32a. A verdict in petitioners' favor would necessarily reflect a finding that respondent could comply with applicable state-law duties of care only by altering the product specifications or labeling that had been reviewed and approved by the FDA. Imposition of tort liability on the basis of such a finding would entail the application of state-law requirements that are "different from, or in addition to," 21 U.S.C. 360k(a)(1), the federal requirements applicable to the device, and that "relate[] to the safety or effectiveness of the device," 21 U.S.C. 360k(a)(2).

The FDA is the expert agency charged by Congress with balancing the risks and benefits of medical devices under the FDCA, and the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application. When the FDA has concluded that a particular medical device is safe and effective for use and has approved the device for marketing, it would undermine the regulatory scheme established by Congress for a jury adjudicating a state-law claim to determine that the same device is defectively designed. Similarly, when the FDA concludes that a particular warning label strikes an appropriate balance

between properly notifying users of potential dangers and ensuring that beneficial and possibly life-saving uses of the device are not deterred, a jury should be precluded from deciding that different warnings ought to have been given.

3. In *Bates*, this Court construed the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b) (quoted in *Bates*, 544 U.S. at 439). FIFRA prohibits the sale of "misbranded" products and states that a pesticide is misbranded if its labeling contains "false or misleading" statements, "does not contain adequate instructions for use," or "omits necessary warnings." *Bates*, 544 U.S. at 438. That misbranding prohibition applies to pesticides that are registered with the Environmental Protection Agency (EPA). *Ibid.* The Court held in *Bates* that FIFRA did not preempt the plaintiffs' state-law damages claim alleging a tortious failure to warn so long as the elements of the state cause of action were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. See *id.* at 447. The Court "emphasize[d]," however, that "a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453.

The FDCA also prohibits the distribution of misbranded devices, see 21 U.S.C. 331(a)-(c), and a device is deemed misbranded if, *inter alia*, "its labeling is false or misleading in any particular," or the device "is dangerous to health when used in the * * * manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 352(a) and (j). The misbranding prohibition applies to products that have received PMA approval. The federal requirements that result from the PMA process have preemptive effect, however, and as explained below, the

possibility of federal misbranding liability does not alter that result. See pp. 15-16, *infra*. In any event, petitioners in their certiorari petition do not advance the theory that their state-law claims are preserved because the relevant state-law requirements parallel the FDCA's misbranding provisions. Cf. note 4, *infra*. Indeed, petitioners do not even cite the FDCA's misbranding provisions. Nor did the court of appeals address that issue; it considered only whether the PMA approval process itself results in "requirement[s]" under 21 U.S.C. 360k(a), and whether state common law imposes corresponding state "requirement[s]." This case therefore would not present an occasion for the Court to consider the viability of such a theory.

Such a theory would be unavailing in any event. The process of agency review under FIFRA with regard to the label language at issue in *Bates* differs in important respects from the process by which the FDA decides whether to grant premarket approval for particular Class III devices. The plaintiff farmers in *Bates* alleged that the label of a pesticide manufactured by the defendant had failed to warn of the potential for the pesticide to damage the farmers' peanut crops. See 544 U.S. at 434-435. Under FIFRA, EPA reviews pesticides and their labeling to determine whether the pesticide causes unreasonable adverse effects on human health or safety or the environment, but EPA does not evaluate the efficacy of the product, including its potential to harm crops or cause other property damage, and the agency does not review the accuracy of any statements about efficacy on the proposed labeling for the product. *Id.* at 440. EPA therefore had not determined whether the label at issue in *Bates* had adequately warned farmers of the potential for damage to their crops. See *ibid.* (noting that EPA had "never passed on the accuracy of the statement in [the pesticide's] original label recommending the product's use 'in all areas where peanuts are grown"). In the instant case, by contrast, petitioners' challenge to the safety and efficacy of the Evergreen Balloon Catheter goes

directly to matters as to which the FDA conducted a rigorous agency review in the PMA process—a review that culminated in the FDA's finding that the Evergreen Balloon Catheter *does* provide "reasonable assurance of safety and effectiveness" and that the labeling is not "false or misleading." See 21 U.S.C. 360e(d)(1)(A).[4]

Furthermore, the Court explained in *Bates* that FIFRA does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. Under the FDCA, by contrast, the FDA is vested with centralized authority in order to promote uniformity of regulation, including the authority under 21 U.S.C. 360k(b) to decide whether exceptions to preemption of state law should be allowed.

4. In its amicus brief filed at the petition stage at the Court's invitation in *Smith Industries Medical Systems, Inc. v. Kernats*, cert. denied, 522 U.S. 1044 (1998), the United States took the position that the FDA's grant of premarket approval for a medical device does not itself establish federal "requirement[s]" for the device within the meaning of Section

---

[4] As a general matter, 21 U.S.C. 360k(a) does not preempt common-lawsuits in which the duty of care is defined by federal law and a State simply provides additional remedies for violations of the federal standard. See *Lohr*, 518 U.S. at 494-497; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Consistent with that principle, the court of appeals correctly held that petitioners' "negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a; see note 3, *supra*. Adjudication of the negligent-manufacturing claim would not implicate any FDA finding, since the agency has made no individualized determination whether a particular catheter conforms to the approved product specifications. With respect to the adequacy of the product specifications themselves, however, the FDA found that there was reasonable assurance of safety and effectiveness of the device, and that the labeling was not false or misleading, when it approved respondent's PMA application.

360k(a). U.S. Br. at 14-17, *Kernats, supra* (No. 96-1405). The position taken in the government's brief in *Kernats* was based upon the FDA's interpretation of the MDA and the agency's characterization of its role in the administrative process at that time, as reflected in a proposed interpretive rule that was appended to the brief and published shortly after the brief was filed. See 62 Fed. Reg. 65,384, 65,387 (1997). That proposed rule, however, was subsequently withdrawn. See 63 Fed. Reg. 39,789 (1998).

The FDA has since reexamined the issue and determined that the position it announced at the time of the filing in *Kernats* was erroneous. The FDA's current position was set forth in an amicus brief filed by the United States on May 14, 2004, in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). See *Horn*, 376 F.3d at 170-173 (discussing the FDA's position set forth in the amicus filing). The government explained in the amicus brief in *Horn* that the prior position did not adequately reflect either the highly detailed nature of the process by which the FDA reviews applications for premarket approval, or the constraints that premarket approval places on manufacturers who subsequently wish to change a device's specifications. U.S. Amicus Br., *Horn v. Thoratec, supra*, at 28 (No. 02-4597); see generally *id.* at 6-11, 15-17, 20-21, 25-27. The government's position in *Kernats* is also inconsistent with the risk-management principles that the FDA currently follows, which recognize that over-warning may be detrimental to the public health. See, *e.g., id.* at 29; 71 Fed. Reg. 3935 (2006) (explaining that additional state requirements governing disclosure of drug-risk information "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use," and that "[e]xaggeration of risk could discourage appropriate use of a beneficial drug"). This Court held in *Lohr* that the FDA's views on preemption questions under 21 U.S.C. 360k are entitled to "substantial weight." 518 U.S. at 496.

B. The Decision Of The Court Of Appeals Does Not Warrant Review

The Second Circuit's resolution of the preemption question raised in this case is consistent with the rulings of the great majority of federal and state appellate courts that have addressed the issue since *Lohr*. During that period, all but one of the federal courts of appeals to decide the issue have held that premarket approval of a medical device preempts state tort claims challenging the safety or efficacy of a product that was designed, manufactured, and labeled in compliance with the terms of the premarket approval order. See Pet. App. 24a-38a; *Horn*, 376 F.3d at 166-180; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 486-490 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 575-585 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-237 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001); see also *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 791-799 (8th Cir. 2001) (en bane) (finding federal preemption based on approval of device pursuant to regulatory precursor of premarket approval process), cert. denied, 535 U.S. 1056 (2002); but see *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369-1382 (11th Cir. 1999) (holding that comparable claims were not preempted). Similarly, all but one of the state supreme courts to rule on this issue have held that analogous suits are preempted by federal law. See *Green v. Dolsky*, 685 A.2d 110, 115-118 (Pa. 1996), *cert. denied*, 520 U.S. 1168, and 520 U.S. 1212 (1997); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 514-517 (R.I.), cert. denied, 522 U.S. 952 (1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 366-377 (Tex.), cert. denied, 524 U.S. 954 (1998); but see *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151-1154 (Ill. 1999).[5]

---

[5] Petitioners contend that three additional cases are in conflict with the weight of authority holding that the FDA's premarket approval of a medical device preempts state tort claims under Section 360k(a). See Pet. 3

Moreover, the decisions in *Goodlin* and *Weiland*, which rejected preemption defenses similar to that raised by respondent here, were issued in 1999, when the law in this area was relatively undeveloped and when the stated view of the FDA, as set forth in the amicus brief filed by the United States in *Kernats* (see pp. 16-17, *supra*), was that the PMA approval process does not impose "requirement[s]" under 21 U.S.C. 360k(a) and that claims like petitioners' were not preempted. Since that time, several federal courts of appeals and state supreme courts have sustained analogous preemption defenses, and no such court has issued a contrary ruling. And since that time, the FDA has reassessed the issue and has concluded that the PMA approval process does result in "requirements" and that state tort claims challenging the safety or efficacy of PMA-approved devices are therefore preempted under 21 U.S.C. 360k(a). See p. 17, *supra*.

The courts in *Goodlin* and *Weiland* had no opportunity to take into account the later-developing majority view among the federal and state appellate courts. Nor did the courts in *Goodlin* and *Weiland* have the opportunity to consider the current position of the FDA, the expert agency charged by Congress with administering the FDCA. In any future decision concerning Section 360k's preemptive scope, those courts would be required to give "substantial weight" to the FDA's position. *Lohr*, 518 U.S. at 496.

(citing *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S. 1005 (1998)); Pet. 14 (citing *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004)). Those cases are readily distinguishable. None of them involved devices for which the FDA had approved a PMA application before the conduct that was alleged to be the basis for liability. See *Oja*, 111 F.3d at 787, 789; *Niehoff*, 950 S.W.2d at 817; *New Womyn*, 679 N.W.2d at 597. In *Oja* and *Niehoff*, moreover, the courts held that liability under state tort law or other state law of general applicability would not result in the imposition of a state "requirement," see *Oja*, 111 F.3d at 789; *Niehoff*, 950 S.W.2d at 822—a premise that was subsequently rejected by this Court in *Bates*, see 544 U.S. at 443; p. 12, *supra*.

In light of those intervening developments, the Eleventh Circuit and the Illinois Supreme Court may reconsider their earlier approach should this issue arise in future cases litigated within those jurisdictions. Under these circumstances, the narrow split in authority does not warrant this Court's review. This Court has repeatedly denied certiorari petitions that presented questions concerning the preemptive effect of the FDA's issuance of premarket approval for Class III medical devices. See *McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin v. Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 534 U.S. 818 (2001); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998); *Fry v. Allergan Med Optics*, 522 U.S. 952 (1997); *Green v. Dolsky*, 520 U.S. 1168 (1997); *Collagen Corp. v. Green*, 520 U.S. 1212 (1997). There is no reason for a different result here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

PAUL D. CLEMENT
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
MALCOLM L. STEWART
Assistant to the Solicitor General
DOUGLAS N. LETTER
SHARON SWINGLE
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

DANIEL MERON
General Counsel

SHELDON T. BRADSHAW
Associate General Counsel
Department of Health and Human Services
Rockville, MD 20857

May 2007